

REMARKS

Reconsideration of this Application is respectfully requested.

Claims 35-40 and 44-59 are pending. Claims 48-59 have been withdrawn from consideration as directed to a non-elected invention.

In the Office Action of August 25, 2004, the Examiner set forth a number of grounds for rejection. These grounds are addressed individually and in detail below.

Objection to the Specification

The specification stands objected to based on the use of the trademark GVAX. The specification has been amended as set forth above. A generic description for the term GVAX is provided in the specification at page 25, lines 30-34.

Rejections Under 35 U.S.C. § 103(a)

Claims 35-39 and 44-47 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Sanda et al. in view of Savarese and further in view of Thomas et al. for the reasons set forth on pages 4-6 of the Outstanding Office Action.

The Examiner specifically relies upon Sanda et al. as the primary reference. The Examiner correctly notes that Sanda et al. does not teach LnCaP, PC3 or DU145 cells, all which are human prostate cell lines recited in the claims. The current invention is based on the fact that the claimed compositions elicit an immune response to a human prostate tumor-associated antigen in a human subject. In contrast to the claimed human LnCaP, PC3 and DU145 prostate cancer cell lines and the data from human patients provided in the examples of instant applications, Sanda et al. is directed to an animal model that relies on a malignant rat prostate tumor line and the use thereof in a rat model and lacks teaching or suggestion regarding a humoral immune response. Sanda et al.

does not teach or suggest a composition for generating a humoral immune response to a human prostate tumor-associated antigen having an approximate molecular weight selected from the group consisting of 250 kD, 160 kD, 150 kD, 31 kD, 26 kD and 14 kD, as currently claimed.

The secondary references, Savarese and Thomas are relied on by the Examiner for teaching LnCaP, PC3 and DU145 cells and how to culture them and the use of GM-CSF secreting whole tumor vaccines, respectively. The Examiner concludes that it would have been obvious to make and use LnCaP, PC3 and DU145 cells engineered to express GM-CSF.

The secondary references, Savarese et al. and Thomas et al. do not compensate for the lack of teaching in Sanda et al. Relative to a composition for generating a humoral immune response to a human prostate tumor-associated antigen having an approximate molecular weight selected from the group consisting of 250 kD, 160 kD, 150 kD, 31 kD, 26 kD and 14 kD, where the response occurs in a human subject, as currently claimed. The examiner argues that an immune response to a human prostate tumor-associated antigen having an approximate molecular weight selected from the group consisting of 250 kD, 160 kD, 150 kD, 31 kD, 26 kD and 14 kD appears to be a consequence of administering the claimed composition. Applicants respectfully disagree.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

Furthermore, the CAFC in *In re Sang Su Lee* states, teaching of references can be combined only if there is some suggestion or incentive to do so. *In re Sang Su Lee* (Fed. Cir. January 18, 2002) (quoting *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577 (Fed. Cir. 1984)). Particular findings must be made as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed. *Id.* In this case, absent the invention as a roadmap, one of skill in the art

would not combine a reference directed to a rat tumor model, Sanda et al., with a reference directed to human prostate cell lines, Savarese et al.

Furthermore, even if one were to combine the cited references there is no suggestion of a humoral immune response to a human prostate cancer antigen, let alone the particular combination of antigens recited in the claims.

Accordingly, this ground of rejection has been obviated and withdrawal of the 35 U.S.C. §103 rejection is respectfully requested.

CONCLUSION

Applicants respectfully request that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to contact Linda R. Judge (Reg. No. 42,702) at 415-659-7035.

Respectfully submitted,

PIPER RUDNICK LLP



Steven B. Kelber
Registration No. 30,073
Attorney of Record

1200 Nineteenth Street, N.W.
Washington, D.C. 20036-2412
Telephone No. (202) 861-3900
Facsimile No. (202) 223-2085

Linda R. Judge
Registration No. 42,702